

REMARKS

The Office Action has been carefully reviewed. Claims 1, 2, and 4-9 are allowed. Claims 18-52 also presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 18-52 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The examiner states that it is unclear whether the biologically active compounds are included in the claimed pharmaceutical composition, or are merely administered at the same time or in the same therapy as the claimed composition. Applicants have now amended claims 18 and 19 to make clear that the pharmaceutical composition is administered to a subject after being processed in combination with or without a biologically active compound.

Claims 18 and 20-52 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner's helpful suggestion for amending claim 18 to overcome this rejection is adopted.

Claim 21 has been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The amendment to claim 21 is believed to obviate this rejection.

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Claims 18, 20, and 21-52 remain rejected under 35 U.S.C. §112, first paragraph, because the examiner holds that the specification, while being enabling for a composition comprising SEQ ID NO:6 or derivatives thereof varying from SEQ ID NO:6 by one amino acid residue, does not reasonably provide enablement for a composition comprising any homologue of SEQ ID NO:6. This rejection is respectfully traversed.

Applicants believe that the specification does indeed reasonably provide enablement for a polypeptide as defined in claim 18 when the state of the art is taken into account in view of the guidance in the disclosure, particularly at page 15, lines 4-24 and page 28, lines 10-17 of the present specification. For example, WO98/10072, at page 9, second to third paragraph, shows the state of the art. It should be noted that a physicochemical property "(6) assay being detected with a monoclonal antibody specific to the above-identified polypeptide or the homologous polypeptide," is now added to claim 18.

Applicants further emphasize that the amino acid sequence of SEQ ID NO:6 is a novel sequence which had not been known at the time the claimed invention was made, and it would be too restrictive for the applicants to delete the reference to "homologue of SEQ ID NO:6" from claim 18. If claim 18 were amended to delete the reference to homologues, then any third party would easily obtain such a homologue based on the

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disclosures in the present specification and the state of the art by conducting substantially the same invention as claimed in claim 18 without any risk of infringement. Such an action of a third party would ruin applicants' investment in effort, time and expense spent to complete the presently claimed invention.

Attached hereto is a copy of Hwang et al. *Cancer Gene Therapy*, 11:397-407 (2004), which discloses a mutant of human IL-18 produced by two point mutations. It should be noted that such a mutant would be excluded from claim 18 if the recitation of "homologue" is deleted from claim 18 in accordance with the examiner's position.

Applicants have noted the examiner's comments at page 5, in the second paragraph, that:

There has been no showing that the murine IGIF of SEQ ID NO:4 would be capable of inducing interferon-gamma production in human cells as required by the claims.

Applicants however do not agree with the examiner. Attached hereto is a copy of Taniguchi et al., *Journal of Immunological Methods*, 217:97-102 (1998), where it is shown that murine IL-18 binds to cells derived from human and acts on cells to induce interferon-gamma production. It is therefore respectfully submitted that the examiner's reasoning is incorrect.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

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Claims 18, 20, and 21-52 remain rejected under 35 U.S.C. §112, first paragraph. The examiner states that the specification does not provide adequate support for claims to the genus of all homologues to the interferon-gamma inducing factor (IGIF) of SEQ ID NO:6. This rejection is respectfully traversed.

Applicant would like to point out that claim 18 does not claim all homologues to the interferon-gamma inducing factor (IGIF) of SEQ ID NO:6, but only those with the recited physiochemical properties (1) to (6).

Furthermore, amended claim 18 contains a new recited physicochemical property of "(6) assay". Applicants believe that one of ordinary skill in the art would easily screen and find out the claimed homologous polypeptide in accordance with the physicochemical property even though claim 18 provides no amino acid sequence identification. It is further believed that physicochemical properties (1) to (6) would provide enough information for a skilled person to identify the claimed homologous polypeptide. The physicochemical properties (1) to (6) have full support in the specification as originally filed.

On page 9 of the Office Action, the examiner cites two decisions from the Court of Appeals for the Federal Circuit and states that identifying a genus through functional language is permissible when such functional language is accompanied by a "known or disclosed correlation between function and structure",

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and that "a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated." However, applicants believe that claim 18 specifies correlation between function and structure. The physicochemical property (1) recites "wherein said homologous polypeptide has substantially the same physicochemical properties and biological activity as the polypeptide of SEQ ID NO:6." This is "function". The physicochemical properties (3) to (6) are considered to be "function". On the other hand, the amino acid sequence as defined in the physicochemical property (i) corresponds to "structure". Applicants therefore believe that claim 18 satisfies the first criterion posed by the court decision.

Furthermore, the specification discloses a number of "species", as discussed above with regard to the lack of enablement rejection, which are believed to support the homologous polypeptide, i.e., "genus". In this regard, applicants consider claim 18 to satisfy the second criterion posed by the court decision.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, applicants believe the claims comply with 35 U.S.C. §112 and define patentable subject matter

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warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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By

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